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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,866	10/10/2006	Dirk Werling	E072 1070.1	9180

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EXAMINER	
HORNING, MICHELLE S	
ART UNIT	**PAPER NUMBER**
1648	

MAIL DATE	DELIVERY MODE
11/10/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/566,866	WERLING, DIRK	
	Examiner	Art Unit	
	MICHELLE HORNING	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 August 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6,9-12,18,19,21-27,29,38,45-48,50,52-64,66-71 and 73-81* is/are pending in the application.

4a) Of the above claim(s) *12, 22-27, 29, 45-48, 50, 55, 60-64, 66-68* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6, 9-11, 18, 19, 21, 38, 52-54, 56-59, 69-71, 73-81* is/are rejected.

7)☒ Claim(s) *73-75* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/25/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is responsive to communication filed 8/25/2010.

Claims 6, 9-11, 18, 19, 21, 38, 52-54, 56-59, 69-71 and 73-81 are under current examination.

Any rejection(s) and/or objection(s) not reiterated herein have been withdrawn.

Examiner's Comment

It is noted for reasons of record that the claims are directed to the *full-length* gp120 protein; see REMARKS filed 8/25/2010. Thus, the claims will be examined accordingly.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6, 9-11, 18, 19, 21, 38, 52-54, 56-59, 69-71 and 76-81 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to (in part) an immunogenic compound comprising (i) HIV gp120 and (ii) an antigen wherein the antigen is associated with a disease of a companion or a farm animal, wherein the antigen elicits an immune

response to the disease, wherein the gp120 and the antigen each comprise a polypeptide and both are present in the same polypeptide chain.

The following quotation from section 2163 of the MPEP is a brief discussion of what is required in a specification to satisfy the 35 U.S.C. 112 written description requirement for a generic claim covering several distinct inventions:

> The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice (see i)(A), above), reduction to drawings (see i)(B), above), or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus (see i)(C), above). See Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406.
>
> A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

Thus, when a claim covers a genus of inventions, the specification must provide written description support for the entire scope of the genus. Support for a genus is generally found where the applicant has provided a number of examples sufficient so that one in the art would recognize from the specification the scope of what is being claimed or through disclosure of a functional characteristic of the claimed genus coupled with a known or disclosed non-functional characteristic (structure) that correlates to the function.

As noted above, the claims are drawn to (in part) an immunogenic compound comprising (i) HIV gp120 and (ii) an antigen wherein the antigen is associated with a disease of a companion or a farm animal, wherein the antigen elicits an immune response to the disease, wherein the gp120 and the antigen each comprise a polypeptide and both are present in the same polypeptide chain.

The instant specification describes a compound for the immunization of an animal comprising a moiety which selectively binds to a dendritic cell in the animal and an antigen. The moiety, HIV gp120, selectively binds DC-SIGN; see abstract. The instant specification provides adequate description for the isolation of bovine DC-SIGN DNA sequences (see p. 36, Example 7) and adequately shows that the bovine DC-SIGN successfully binds gp120 protein which successfully leads to an immune response to antigen RSV F protein (see p. 28-31). Note that with respect to an antigen, the claims are broad in view of the antigen's structure which may encompass any and all antigens derived from many disease states; in contrast, the claims are functionally limited to an antigen that is required to elicit an immune response to the animal's disease. Both the instant specification and the claims provide that the antigens may be tumor or cancer-associated (see p. 11 and at least instant claim 10).

It is well-known in the art that many antigens are self-antigens, including those associated with allergies, tumors or cancers. In contrast to foreign antigens, self-antigens are defined as any constituent of the body's own tissues capable of stimulating autoimmunity and it is known that some cancer patients will be immunologically "tolerant" to some tumor antigens. See US Patent 6235280 which provides a general description of self-antigens associated with a tumor, such as carcinoembryonic antigen. The instant specification fails to provide that a compound comprising an HIV gp120 and such a self-antigen would successfully lead to the antigen eliciting an immune response to the disease, such as cancers, etc. Note that it is neither clear nor predictable from the instant specification.

Because of the lack of adequate support for any and all antigens in the compound as claimed in eliciting a response to the antigen, the claims are rejected for lacking adequate written description in the instant specification.

Allowable Subject Matter

Claims 73-75 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

No claim is allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELLE HORNING whose telephone number is (571)272-9036. The examiner can normally be reached on Monday-Friday 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ZACHARIAH LUCAS can be reached on 571-272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. H./
Examiner, Art Unit 1648

/Zachariah Lucas/
Supervisory Patent Examiner, Art Unit 1648